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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,530	08/31/2005	Leonard H. Rome	14399-1US	1636
23676 7590 01/10/2008 SHELDON MAK ROSE & ANDERSON PC 100 East Corson Street Third Floor PASADENA, CA 91103-3842			EXAMINER GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	
			MAIL DATE	DELIVERY MODE
			01/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/547,530

Applicant(s)

ROME ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 50, 52, 54-56, 58 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 50, 52, 54-56, 58 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Applicant's election without traverse of Group I, Claims 1-5, 50, 52, 54-56, 58 and 60 in the reply filed on 10/22/07 is acknowledged.

35 USC 112, 1st Paragraph Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 50, 52, 54-56, 58 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants claim a method of using vaults as carrier molecules to deliver one or more than one substance to an organism, or to a specific tissue or to specific cells, or to an environmental medium, comprising: a) providing vaults; b) incorporating the one or more than one substance into the vaults; and c) administering the vaults comprising the one or more than one substance to the organism, to the specific tissue, to the specific cells, or to the environmental medium.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Teletronics*, 8

USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

1) Unpredictability of the art. The art concerning vaults, the functions of vaults, the molecules transported in, or by, vaults, the compositions of vaults (i.e. do all vaults contain the three vault RNAs (hVR1, hVR2 and hVR3) or are there subsets of vaults containing a subset of vault RNAs), the function of the vault RNAs, etc. are poorly known or are entirely unknown (see for example Suprenant, *Biochemistry*, 2002, Vol. 41, No. 49, pp. 14447-14454; van Zon et al., *Biochem. Biophys. Res. Comm.* 2002, Vol. 291, pp. 535-541, both references already of record). Since it is not known how vaults normally function and what molecules they may normally deliver, it must be considered that the art concerning recombinantly engineering vaults to deliver specific substances to specific cells or tissues is extremely unpredictable and at a totally experimental stage. Indeed, recent research calls into question the role(s) vaults may play in intracellular transport and said research indicates that vaults may not have a role in the main nuclear import/export pathway (van Zon et al., *Exp. Cell Res.*, 2006, Vol. 312, pp. 245-255).

2) State of the art. The state of the art with regard to recombinantly engineering vaults to transport and deliver substances to target cells or tissues is nil.

3) Scope of the invention. The scope of the invention is extremely broad with the broadest claims reading on methods of delivering any substance to any cell or tissue or any organism by use of vaults or vault like particles from any source.

4) Amount of guidance provided. Applicants, in the disclosure of the priority document 60/453,800, contemplate fusing peptides to the N terminus of the major vault protein (MVP) and prepare vault like structures comprising luciferase tagged with the vault associated poly(ADP-ribosyl)ating polymerase (VPARP) INT domain (said engineered particles lack VPARP). Applicants do not use said vault like structures to deliver substances to target cells or tissues or environmental media. It is unclear if said vault like structures could function to deliver any given compound to a given cell or tissue in a biologically active form. Outside of fusing peptides to the MVP or incorporating a VPARP INT domain into a polypeptide of interest, it is unclear how applicants would encapsidate a non-protein compound into a vault or vault like structure. Also, it is unclear if the vault like structures formed by applicants can be referred to as vaults since they do not possess all of the proteins normally found in vaults.

5) Nature of the invention. The invention involves manipulation of poorly known cellular structures (vaults) which have not previously been manipulated to deliver compounds of interest to target cells.

6) Level of skill in the art. The level of skill in the art is high; however, given the unpredictability of the art, the poorly developed state of the art, the lack of guidance provided by applicants and the prior art, and the broad scope of the invention, it must be

considered that the skilled artisan would have had to have conducted essentially trial and error experimentation in order to attempt to practice the claimed invention.

Given the above analysis of the factors which the courts have determined are critical in determining whether a claimed invention is enabled, it must be concluded that the skilled artisan would have had to have conducted undue and excessive experimentation in order to enable the claimed invention.

The claimed invention is free of the art. Vaults have been known in the art for almost 20 years but their biological functions are still poorly known. Given the poorly understood nature of these structures, the prior art is mainly concerned with attempting to elucidate the biological functions of these structures and does not contemplate engineering vaults to deliver compounds of interest into target cells or tissues (for a review of the art on vaults, see Suprenant, cited above).

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


DAVID GUZO
PRIMARY EXAMINER

David Guzo
December 31, 2007